

**REMARKS**

**I. INTRODUCTION**

Independent claims 27 and 37 have been amended in response to the objection to the claims, and in order to clarify the subject matter recited therein. New claims 56 and 57 have been added. Accordingly, claims 27-34, 36-50 and 52-57 are now under consideration in the present application. It is respectfully submitted that no new matter has been added.

**II. OBJECTIONS TO THE SPECIFICATION**

In the Office Action, the Examiner objects to the Specification because it allegedly fails to provide proper antecedent basis for the claimed subject matter of dependent claims 54 and 55. The Examiner contends that the Specification of the present application allegedly fails to disclose that the energy source is provided to activate the fluid to destroy at least one of a plurality of cells and a tissue within the target area. Applicants respectfully disagree.

The specification, e.g., in paragraph [0015], states: “[t]he photodynamic fluid may include the type of fluids which absorb energy (e.g., energy in the form of light) over a predetermined range of frequencies and produce a chemical reaction, such as, for example, a chemical reaction which produces a toxin or other actor capable of damaging or killing cells and/or tissue.” Further, in paragraph [0018], it states: “[s]pecifically, because the target area 130 receives the fluid 150, the transmission of the energy 160 to the target area 130 may generate a chemical reaction which can damage or destroy cells and/or tissue associated with the target area 130.” Because

the photodynamic fluid is capable of absorbing energy and producing a chemical reaction that produces a toxin, which in turn damages or kills cells and/or tissue, the specification clearly supports and describes the subject matter recited in claims 54 and 55, e.g., the energy source activating the fluid to destroy at least one of a plurality of cells and a tissue within a target area.

Accordingly, Applicants respectfully submit that the objection to the Specification is inappropriate, and should be withdrawn.

### **III. OBJECTION TO THE CLAIMS**

Claims 27-34, 36-50 and 52-55 are objected to because of the following informalities: Claims 27 and 37 recite "the liquid" in line 6. The Examiner states that there is insufficient antecedent basis for this recitation in the claims.

As the Examiner shall ascertain, claims 27 and 37 have been amended to recite "the fluid" instead of "the liquid", for which proper antecedent basis is provided. Accordingly, Applicants respectfully request that the objection to claims 27-34, 36-50 and 52-55 be withdrawn.

### **IV. REJECTIONS UNDER 35 U.S.C. § 112**

Claims 27-34, 36, 53 and 54 are rejected under 35 U.S.C. § 112, first paragraph as being allegedly indefinite for failing to comply with the written description requirement. The Examiner states that the recitation of the liquid being provided to be received only by those areas of the heart having a metabolism which is less than or

equal to the predetermined metabolism is allegedly not described in the specification and in fact, is contradictory to paragraph [0017].

As the Examiner shall ascertain, independent claim 27 has been amended to recite that the liquid is provided to be received only by those areas of the heart having a metabolism which is greater than or equal to the predetermined metabolism, without being received by those areas of the heart equal to the predetermined metabolism. Such recitation is consistent with the description provided in, e.g., paragraph [0017] of the specification of the present application.

In view of the above, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph rejection of claims 27-34, 36, 53 and 54.

**V. REJECTIONS UNDER 35 U.S.C. § 102(b)**

Claims 27-34, 36-50 and 52-55 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent Application Publication No. 2002/0095197 to Lardo et al. (hereinafter "Lardo"). Claims 27-34, 36-50 and 52-55 stand further rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 6,811,562 to Pless (hereinafter "Pless"). Applicants respectfully assert that neither Lardo nor Pless discloses the subject matter recited in amended independent claims 27 and 37 for at least the reasons provided herein below.

Independent claims 27 and 37 were amended above merely to clarify the subject matter recited therein. Specifically, independent claims 27 and 37 recite that "the fluid is provided to be received only by those areas of the heart having a

metabolism which is greater than or equal to the predetermined metabolism, without being received by those areas of the heart having a metabolism less than the predetermined metabolism." Support for such amendment to these claims can be found throughout the specification, and, e.g., in paragraph [0017] thereof.

Lardo describes methods and devices for treating and curing cardiac arrhythmias using photo-chemotherapy or photodynamic therapy. (See Lardo, ¶ [0026]). The method of Lardo includes administering a photosensitizing agent to a patient's cardiac tissue, from which abnormal signals causing arrhythmias arise and/or by normal tissues that assist in sustaining arrhythmias. (See *id.*, ¶¶ [0027-0028]). The agent may be administered in a variety of ways, including systemically, via an angioplasty catheter balloon, or by perfusing the agent directly into the coronary arteries. (See *id.*, ¶¶ [0028-0032]). The photosensitizing agent may then be activated through a variety of illumination methods. (See *id.*, ¶¶ [0027] and [0035]).

Pless describes procedures and devices for treating cardiac tissue by forming lesions in the tissue using photodynamic therapy techniques. (See Pless, column 1, lines 7-9). In particular, Pless discloses a means of detecting cardiac arrhythmias by using an electrocardiogram (EKG) to detect the electrical activity within the heart. (See *id.*, column 2, lines 47-60). Further, a method of Pless is provided that includes introduction of a photodynamic drug through, for example, an intravenous injection or local administration. (See *id.*, column 9, lines 42-45). Additionally, Pless discloses a use of a light source to focus energy on a specific region on the heart to excite the photodynamic drug once it has been administered. (See *id.*, column 1, lines 19-41 and 47-59).

However, Lardo and Pless both fail to disclose each and every element of the claims, and in particular, that the fluid is provided to be received only by those areas of the heart having a metabolism which is greater than or equal to the predetermined metabolism, without being received by those areas of the heart having a metabolism less than the predetermined metabolism, as explicitly recited in independent claims 27 and 37.

For example, as described in the specification of the above-identified application, the target area 130 can include scar tissue, such as the scar tissue generated after the subject 110 experiences a heart attack. The scar tissue may have a predetermined metabolic rate, and the liquid 150 may be selected to have predetermined characteristics for such rate. For example, the predetermined metabolic rate *can be greater than the metabolic rate that is associated with normal heart tissue*. Moreover, e.g., the liquid can be selected such that the liquid concentrates in tissue which has a metabolic rate which is greater than or equal to the predetermined metabolic rate, but does not concentrate in tissue having a metabolic rate which is less than the predetermined metabolic rate. Consequently, e.g., when the liquid 150 includes these predetermined characteristics, regardless of whether the liquid 150 is introduced systemically or locally, the liquid 150 may be received by the target area 130, but would not be received by those portions of the heart 120 which are outside the target area 130. (See paragraph [0017]).

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindeman Maschinenfabrik GMBH v. American Hoist and Derrick Company*, 730 F.2d

1452, 1458, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). In clear contrast to the Applicants' claimed invention, Lardo and Pless do not disclose that the fluid is provided to be received only by those areas of the heart having a metabolism which is greater than or equal to the predetermined metabolism, without being received by those areas of the heart having a metabolism less than the predetermined metabolism, as recited in amended independent claims 27 and 37 as discussed herein.

In the Examiner's response to applicants' arguments on page 5 of the present Office Action, the Examiner contends that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The Examiner further asserts that if the prior art structure is capable of performing the intended use, then it meets the claim. The Examiner alleges there are no structural differences between the claimed invention and prior art. (See Office Action of December 14, 2007, p. 5, lines 7-20).

However, amended independent claims 27 and 37 clearly recite a fluid delivery system structured to introduce a fluid to a target area of a heart of a subject, and the fluid delivery system is structured such that the fluid is provided to be received *only by those areas of the heart having a metabolism which is greater than or equal to the predetermined metabolism, without being received by those areas of the heart having a metabolism less than the predetermined metabolism*. Therefore, there is a clear structural difference between the claimed invention and the prior art. Neither Lardo nor Pless disclose a fluid delivery system structured as recited in claims 27 and

37, and the Examiner cannot point to any section of either Lardo or Pless as disclosing it.

Regarding the § 102(b) rejections of claims which depend from claims 27 and 37, since Lardo and Pless both fail to disclose the features of the independent claims, and the remaining dependent claims recite additional features, Applicants respectfully assert that these claims are also patentable at least because Lardo and Press do not disclose the subject matter recited in independent claims 27 and 37.

Therefore, for at least the reasons as presented herein above, Applicants respectfully request the 35 U.S.C. § 102(b) rejections of claims 27-34, 36-50 and 52-55 under Lardo and Press be withdrawn.

**VI. NEW CLAIMS 56 AND 57**

New claims 56-57 have been added above. Claim 56 depends from claim 54, which depends from independent claim 27, and claim 57 depends from claim 55, which depends from independent claim 37. Support for the claims is provided throughout the specification, and, e.g., in paragraph [0015] thereof. Applicants respectfully submit that the subject matter recited in these new claims is not disclosed in Lardo or Pless. A confirmation that these claims are patentable over Lardo and Pless is respectfully requested.

**VII. CONCLUSION**

In light of the foregoing, Applicants respectfully submit that pending claims 27-34, 36-50 and 52-57 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited. If any issues remain outstanding, the Examiner is invited to contact the undersigned via the telephone number provided below.

Respectfully submitted,

Date: March 14, 2008

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